

S/N 09/850537

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robert J. Sweeney et al.

Examiner: Frances Oropeza

Serial No.: 09/850,537

Group Art Unit: 3762

Filed: May 7, 2001

Docket: 279.159US2

Title: CARDIAC RHYTHM MANAGEMENT SYSTEM WITH ARRHYTHMIA
PREDICTION AND PREVENTION

#13
B. Webb
11/4/03

RESPONSE TO ADVISORY ACTION

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Applicant has reviewed the Final Office Action mailed July 24, 2003 and the Advisory Action mailed October 20, 2003 and responds as follows.

First, the Advisory Action stated that certain claim amendments introduced new issues requiring a new search and further consideration. Accordingly, Applicant is submitting herewith a Request for Continued Examination (RCE) for further consideration of Applicant's previously-submitted September 24, 2003 Response to the Final Office Action.

Second, Applicant thanks the Examiner for the helpful remarks in the Advisory Action explaining the Examiner's interpretation of the term "conditional probability" as used in the claims. *Applicant respectfully requests a telephonic interview, before further examination of the patent application, to briefly discuss Applicant's use of this term.* Applicant believes that such a telephonic interview could advance prosecution or even result in agreement regarding the claims.

In preparation for such a telephonic interview and/or further examination, Applicant offers the following further explanation in response to the Advisory Action's helpful remarks relating to "conditional probability." Claim 45 states that the estimated arrhythmia probability is computed from "a conditional arrhythmia probability associated with the conditioning event that is derived from past observations of instances in which the conditioning event occurs alone or together with the arrhythmia within a specified time period." This is not inconsistent with the well-understood mathematical definition of conditional probability, which states: $P(A|B) = P(A \cap B) / P(B)$. See <<http://mathworld.wolfram.com/ConditionalProbability.html> (visited Sept. 22, 2003)>. In the present context, the well-accepted mathematical definition can be restated as follows: the probability of an arrhythmia given the occurrence of a "conditioning event" is equal to the probability of both the arrhythmia and the conditioning event occurring (e.g., within a

specified time of each other) divided by the probability of the conditioning event occurring. To obtain the conditional probability, $P(A|B)$, the right-hand side of the above equation uses past observations in which the conditioning event occurs together with (e.g., within a specified time of) the arrhythmia, (i.e., $P(A \cap B)$), and past observations in which the conditioning event occurs either with or without the arrhythmia, (i.e., $P(B)$). Then, at the time a prediction of a future arrhythmia is made, $P(A|B)$ and $P(B)$ are known from past observations, which permits prediction of the future arrhythmia as $P(A \cap B) = P(B) \times P(A|B)$. Therefore, the Applicant respectfully submits that the additional claim language cited by the Examiner is in no way inconsistent with the well-accepted definition of conditional probability.

Furthermore, the specification of the patent application provides an example that is consistent with the well-accepted definition of conditional probability. Among other things, the specification of the present patent application states:

In one embodiment, the conditional arrhythmia probability is calculated as a ratio of the number of observed instances in which the conditioning event is followed by an arrhythmia within a specified basic time period, to the total number of observed instances of the conditioning event.

(Application at page 4, lines 13 – 16.) Applicant respectfully submits that this is fully consistent with the common definition of conditional probability set forth above.

The Advisory Action also states:

It is noted that the Applicant defines four embodiments used to derive “conditional arrhythmia probability” in the specification, pages 4 and 5, so it is unclear why the Applicant argues the use of the “ordinary well-understood meaning of conditional probability” when specific embodiments for deriving “conditional probability” have been defined in the specification. It is also noted these embodiments to derive conditional probability are defined in the specification, but not claimed in the claims.

(Advisory Action at 2.) However, as discussed above, the specification does describe conditional probability fully consistent with the commonly accepted definition. (See Application at page 4, lines 13 – 16.) With respect to the Advisory Action’s assertions regarding any embodiments that the Examiner asserts are not claimed in the present claims, Applicant does not admit that such embodiments are not encompassed by the present claims. However, such embodiments (e.g.,

using a Poisson distribution, etc.) are also believed to be fully consistent with the ordinary definition of conditional probability in that they, too, involve observation of past instances in which a conditioning event occurs alone or together with the arrhythmia and forming a resulting conditional probability, as discussed above.

The Advisory Action also states:

The conditional probability as taught by Shapland (col. 1 @ 41 – 52; col. 2 @ 25 – 47; col. 3 @ 12 – 19) is read to be consistent with “conditional probability” as claimed by the Applicant, hence the rejection of record stands.

(Advisory Action at 2.) Applicant respectfully traverses. The first cited portion of Shapland (U.S. Patent No. 5,042,497) reads as follows:

It is another object of the present invention to provide a system for monitoring the neural tone of a patient and taking preventative or curative actions in an implanted device upon the occurrence of changes such as, altered levels of neural tone. It is a further object of this invention to provide a system for monitoring the autonomic neural tone of a patient, monitoring the ECG at the same time and upon an indication of arrhythmia by both the measured electrical activity of the heart and the autonomic neural tone, taking preventative or curative actions in an implanted device in preparation for an impending cardiac arrhythmia event.

(Shapland at column 1, lines 41 – 52.) Applicant respectfully submits that nothing in this passage discloses, teaches, or suggests using a conditional probability derived from past observations of instances in which the conditioning event occurs alone or together with the arrhythmia within a specified time period, as recited in claim 45. Applicant’s reading of this passage is that an arrhythmia is indicated by measuring autonomic neural tone and an ECG signal. Applicant can find no language in this passage about computing a conditional probability that is derived from past observations in which a particular autonomic neural tone or ECG measurement occurs alone or together with the arrhythmia within a specified time period.

The second cited portion of Shapland states:

Referring first to FIG. 1, the arrhythmia prediction and prevention/treatment system is generally shown at 10. The system 10 includes a plurality of autonomic neural monitoring units as shown in block 12. Block 12 is connected to block 14 which includes a plurality of preventative actions to be taken in response to elevated levels of the sympathetic neural tone. Block 12 includes four methods for monitoring the autonomic neural tone. The first method, shown in block 16, determines heart rate variability or respiration rate variability. Heart rate

variability is determined by measuring the interval between heart beats based on sensing and determining the R-R interval. Respiration variability is likewise determined by measuring the interval between respirations. Variability of both parameters is calculated by examining the beat to beat or breath to breath variation as compared to a previously determined standard. Typically, a decrease in variability indicates an elevated sympathetic tone or reduced parasympathetic tone. The second method, shown in block 18, determines the autonomic neural influence of the pumping function of the heart.

(Shapland at column 2, lines 25 – 47.) Again, Applicant respectfully submits that nothing in this passage discloses, teaches, or suggests using a conditional probability derived from past observations of instances in which the conditioning event occurs alone or together with the arrhythmia within a specified time period, as recited in claim 45.

The third cited portion of Shapland states:

Regardless of the method employed to monitor the autonomic neural activity, a threshold is provided, particular to the specific method, which must be at least met to trigger actions in block 14. Basically, a baseline threshold is pre-set or otherwise obtained from previous measured values. Then, the real-time measured data is compared to this threshold value to determine the deviation therefrom and the extent of such deviation.

(Shapland at column 3, lines 12 – 19.) Again, Applicant respectfully submits that nothing in this passage discloses, teaches, or suggests using a conditional probability derived from past observations of instances in which the conditioning event occurs alone or together with the arrhythmia within a specified time period, as recited in claim 45. In particular, Applicant respectfully submits that obtaining a data baseline threshold from previous measured values falls considerably short of computing a conditional probability derived from past observations of instances in which the conditioning event occurs alone or together with the arrhythmia within a specified time period.

Moreover, the cited passage actually teaches away from the language of claim 45. Claim 45 involves comparing an estimated arrhythmia probability to a specified threshold value. By contrast, the cited portion of Shapland apparently compares the actual measured data to a threshold, rather than comparing a probability to a threshold. Applicant believes that this is a clinically significant difference because, among other things, comparing an estimated arrhythmia probability (e.g., computed from one or more conditional probabilities) to a threshold permits

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contributions from various different types of conditioning events to be aggregated in a statistically sound manner, that is, using the actual conditional probabilities associated with the various different types of conditioning events. (*See, e.g.,* Application at page 24, lines 18 – 22.)

Conclusion

Applicant respectfully requests consideration of the above remarks (along with Applicant's previously-submitted September 24, 2003 Response to the Final Office Action) before any telephonic interview and/or further examination. Applicant submits that the claims are in condition for allowance. Withdrawal of all outstanding rejections and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney 612-373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

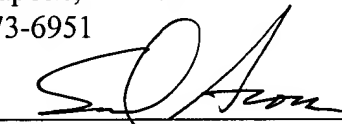
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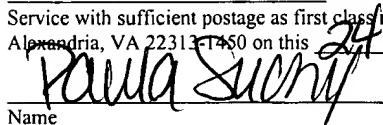


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